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June 27, 2022

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of Wednesday's case management conference.

1. Losartan and Irbesartan Core Discovery

Plaintiffs sent Defendants a list of core discovery topics for losartan and irbesartan. (Ex. 1 hereto). This list is nearly identical to the list of core discovery topics for valsartan, with the addition of nitrosamine test results:

1. For API Manufacturer and Supplier Defendants
    a. Losartan and Irbesartan ANDA file(s)
    b. Losartan and Irbesartan Drug Master File(s)

c. Communications with the FDA relating to or concerning: (1) the ARB recalls, (2) the investigation into the cause of the alleged contamination, (3) efforts to contain, remove or detect the contamination, (4) supplements to the Losartan and Irbesartan Drug Master File re: manufacturing process changes from 2011 to present, (5) all FDA Form 483's[1], Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue, and (6) a list of all United States customers from 2011 to present.
d. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.
e. All nitrosamine test results.

2. For Finished Product/Dose Manufacturer Defendants
   a. ANDA file for each involved finished dosage formulation
   b. Communications with the FDA described in paragraph 1.c. the extent not produced by another responding defendant, the discovery listed in paragraph 1.
   c. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.
   d. All nitrosamine test results.
3. For U.S. Agents for FDA Communications Defendants
   a. To the extent not produced by another responding defendant, the discovery listed in paragraphs 1. and 2. Above
   b. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

Defendants have requested a meet and confer. Plaintiffs ask the Court to order the Parties to complete their meet and confer in time to present this issue to Judge Vanaskie at the next status conference.

[1] Including any reply to FDA Form 483, related subsequent correspondence; the FDA inspection reports and exhibits; responses to that report and exhibits; and any related FDA correspondence and meeting minutes.

2. Deadlines for Motions to Seal Parts of the Briefing Related to Class Certification.

Defendants have requested a nineteen-day extension to meet and confer regarding their potential motions to seal parts of the briefing related to class certification. They also asked to extend the deadline for those potential motions from thirty days after the completion of the briefing to sixty days after the Parties' meet and confer. Plaintiffs do not oppose either request.

3. PFS Deficiencies and Orders to Show Cause.

Plaintiffs will be prepared to address this issue during the case management conference.

Respectfully,

ADAM M. SLATER

Cc: All counsel of record (via ECF)